

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated 13 August 2003 are respectfully requested. A separate petition for a two-month extension of time accompanies this amendment.

I. Amendments

The present amendment amends claims 32 and 92 and cancels claim 67.

II. The Applied Art

All of the outstanding rejections are based on two references – U.S. Patents 5,062,847 (Barnes) and 5,707,362 (Yoon). Barnes suggests a laparoscopic retractor that can be inserted into a body cavity using a trocar. When the device is in place, a trigger 13 may be squeezed to force a series of "retractor pods 15" intoatraumatic contact with the tissue to be retracted. Barnes particularly notes that the retractor pods 15 "may be manufactured from a softer material such as pliable plastic, rubber or latex, so as to minimize the risk of injury to delicate tissue during retraction."

Yoon, like Barnes, suggests using a trocar and cannula to access an anatomical cavity, e.g., the abdominal cavity. The penetrating instrument 20 shown in Figures 1-7, to which the Examiner points in rejecting several claims, includes a cannula 26 that receives a trocar or "penetrating unit 24." A middle member 32 carrying a series of flexible strips 44 is disposed between the cannula 26 and the trocar 24. There is no connection between the trocar 24 and this middle member 32. Figures 1, 6, and 7 of Yoon illustrate a sequence of stages to introduce the penetrating instrument 20 into an anatomical cavity, as discussed in the specification at column 9, line 35-column 10, line 9. As an operator advances the trocar and cannula through the tissue wall W, the force of the tissue around the flexible strips 44 will cause the flexible strips to compress (Figure 6). Once the strips 44 pass through the tissue wall W into the anatomical cavity, they will automatically expand (Figure 7) under the force of a spring 45 (Figure 1). Yoon focuses on this automatic feature in the Summary of the Invention, suggesting it is of particular significance.

III. Rejections under 35 U.S.C. § 102

The Examiner has allowed claims 90, 91, 93-95, and 99. The Examiner also objected to claims 74, 82, and 87 as depending upon a rejected base claim, but indicated that these claims would be allowable if rewritten in independent form. All of the remaining claims in the application, i.e., claims 32-36, 65-68, 70-73, 75, 76, 78-81, 83-86, 88, 92, and 96-98, were rejected as anticipated by either Barnes or Yoon. As explained below, the undersigned respectfully submits that all these rejected claims are allowable over Barnes and Yoon.

A. Claims 32-36, 65, 66, 68, and 70-73 Are Allowable Over Barnes

Claims 32-36, 65-68, and 70-73 were rejected as anticipated by Barnes. Aspects of claim 67 have been incorporated into claim 32 and claim 67 has been rejected, rendering the rejection of claim 67 moot.

Claim 32, as amended, calls for a tissue anchor that includes, among other features, an elongate tube having at least one aperture, an elongate member having a portion sized for axial movement in a bore of the elongate member, and at least one anchor member attached to the elongate member. The anchor member has a free distal end that carries a tissue-penetrating barb. When the elongate member is in its second position, the anchor member projects through the aperture in the elongate tube and extends transversely with its distal end positioned outwardly of the elongate tube. By way of non-limiting example, the particular implementations shown in Figures 13 and 19 have the barbs 312 penetrating into a tissue volume 22 of interest.

As noted above, the laparoscopic retractor of Barnes includes soft, atraumatic pods that are designed to minimize the risk of injury to the tissue being retracted. This is in keeping with the general goals of a laparoscopic retractor, which is merely to temporarily shove organs or the like out of the way to provide a clear space within which to perform a laparoscopic procedure. These atraumatic pods are readily distinguishable from the barbs of the tissue anchor of claim 32. The present anticipation rejection, therefore, must fall.

The undersigned further submits that claim 32 is patentable over Barnes. The very purpose of the pods 15 of Barnes is to limit trauma to tissue being retracted. Employing barbs that are adapted to penetrate into that tissue would directly contradict

the purpose of Barnes' retractor. As it is never obvious to modify a reference in a manner that would destroy its intended utility, Barnes can not render claim 32 obvious. Claims 33-36, 65, 66, 68, and 70-73 all depend from claim 32 and are believed to be patentable at least by virtue of their dependence from an allowable base claim.

B. Claims 75, 76, 78 and 79 Are Allowable Over Yoon

The Examiner has rejected only 4 claims – claims 75, 76, 78 and 79 – as anticipated by Yoon. Claim 75, from which the remaining claims depend, recites a tissue anchor for stabilizing a tissue mass for surgical excision. This tissue anchor generally includes, among other features, a manually controllable actuator comprising an elongate member sized for a close sliding fit within the central bore of an elongate tube. A plurality of manually deployable anchor members is operably connected to the actuator so that the anchor members assume an extended position when the actuator is in its second position. In this extended position, the anchor members project outwardly into the tissue mass and assumes a curved configuration to facilitate stabilization of the tissue mass.

In the present Office Action, the Examiner characterizes the flexible strips 44 of Yoon as "manually deployable anchor members" that are operatively connected to an actuator and that assume a curved configuration when in an extended position. As discussed in the response to the prior Office Action, which made a similar rejection, the undersigned is not sure how the Examiner reads the flexible strips 44 as being operatively connected to the actuator. The middle member 32, which the Examiner characterizes as the actuator, is not directly attached to the flexible strips 44 and the undersigned fails to follow the Examiner's logic in arguing that they are operatively connected thereto.

In addition, the flexible strips 44 of Yoon are specifically designed to be connected at both ends so they can resiliently collapse under the nominal force of the tissue wall W and return to their normal configuration after passing through the tissue wall W. As the strips 44 must collapse for passage through the wall W under this nominal force, the undersigned fails to see how the Examiner can contend Yoon teaches anchor members that are adapted to project outwardly into a tissue mass. Although this point was raised in the prior response, the present Office Action does not

address that issue. The undersigned would be grateful if the Examiner could explain how he can square the automatic collapse flexible nature of Yoon's flexible strips, necessary for their automatic deployment, with this aspect of claim 75.

Claims 76, 78, and 79 depend from claim 75. As claim 75 is believed allowable over Yoon, the undersigned respectfully submits that claims 76, 78 and 79 are also allowable at least by virtue of their dependents from an allowable base claim.

C. Claims 80 and 81 Are Allowable Over Barnes

The Examiner rejected claims 80 and 81 as anticipated by Barnes. Claim 80 calls for a tissue anchor for stabilizing a tissue mass for a surgical excision that includes, among a number of other features, a plurality of manually deployable anchor members. In their extended positions, these anchor members project outwardly into a tissue mass from an aperture in an elongate tube.

As noted above, Barnes suggests using soft,atraumatic pods 15 to avoid damaging tissue being lifted out of the way during a laparoscopic procedure. The undersigned fails to understand how the Examiner reads Barnes as teaching an anchor member that projects into a tissue mass and is adapted to facilitate stabilization of that tissue mass. If the Examiner elects to maintain the present rejection, the undersigned would be grateful if the Examiner would provide a more thorough explanation of how he or she reads Barnes as teaching an anchor member that can project into a tissue mass as called for in claim 80. In the absence of such further explanation, the undersigned respectfully submits that claim 80 and dependent claim 81 are patentable over Barnes.

D. Claims 83-86 and 88 Are Allowable Over Barnes

Aspects of claim 83 are analogous to aspects of claim 80 discussed above. By analogy to the preceding discussion, therefore, claims 83 and dependent claims 84-86 and 88 are patentable over Barnes.

E. Claim 92 Is Allowable Over Barnes

Claim 92, as amended, calls for a tissue anchor that includes, among other features, four anchor members, each of which moves outwardly into the tissue mass to assume a curved configuration within the tissue mass to facilitate stabilization of the tissue mass. As noted above, Barnes employs special pods 15, which may be formed

of a softer plastic material, to limit trauma to the organs and the like the laparoscopic retractor holds back. The undersigned respectfully submits that this specifically teaches away from the anchor members of claim 92.

F. Claims 96 and 97 Are Allowable Over Barnes

Claim 96 requires deploying anchor members such that they curve outwardly and extend into the tissue mass. Again, Barnes actually teaches that specific steps should be taken to prevent the device from damaging tissue in this manner. Claim 96 and dependent claim 97 are, therefore, patentable over Barnes.

G. Claim 98 Is Allowable Over Barnes

Aspects of claim 98 are analogous to aspects of claim 92. By analogy to the prior discussion of claim 92, therefore, claim 98 is also patentable over Barnes.

IV. Conclusion

In view of the foregoing, all of the claims pending in the application comply with the requirements of 35 U.S.C. § 112 and patentably define over the applied art. A Notice of Allowance is, therefore, respectfully requested. If the Examiner has any questions or believes a telephone conference would expedite prosecution of this application, the Examiner is encouraged to call the undersigned at (206) 359-3848.

Respectfully submitted,
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